

### **Remarks**

#### **A. Rejections Under 35 U.S.C. § 112**

In the current Office Action, the Examiner has rejected Claims 1-10 under 35 U.S.C. § 112. Specifically, the Examiner states that “Claims 1 and 5 have closed language with regard to the liquid composition: ‘consisting of’, however, the amounts of the ingredients when added up constitute from 4.78 to 7.1% by volume of the liquid composition ...” (Office Action, p.3). Applicant has amended Claims 1 and 5 to clarify that the liquid components used in the claimed device and method, further require the presence of “92 - 95 percent by volume of a solvent,” such that the constituents recited in Claims 1 and 5 may total 100% by volume of the liquid recited therein. Support for this amendment may be found at Paragraphs [0021] - [0025].

The Examiner further states that Claims 2 and 6 recite “solvent,” without sufficient antecedent basis. (Office Action, p.3). The language added to Claims 1 and 5, namely, “92 - 95 percent by volume of a solvent,” now provides sufficient antecedent basis for “solvent,” as such term is used in dependent Claims 2 and 6.

The Examiner further states that “Claims 4 and 7 recite the closed language: ‘composition consists of an aqueous solution’ and this is followed by the open ended recitation of ‘the aqueous solution containing.’” In response, Applicant has amended Claims 4 and 7 to clarify that a solvent is present, namely, “92-95 percent by volume of water.” In addition, Applicant has deleted the open ended phrase “the aqueous solution containing.”

Applicant respectfully asserts that the foregoing amendments render the pending Claims 1-10 definite, and that the rejections under 35 U.S.C. § 112 should be withdrawn.

## **B. Rejections Under 35 U.S.C. § 103**

The Examiner has maintained the rejection of Claims 1-10 under 35 U.S.C. § 103(a), as allegedly being obvious in view of several prior art references discussed therein. The primary basis for this rejection is that, despite the use of the close-ended “consisting of” transitional phrase in Claims 1 and 5, the “*claims [were] interpreted as open-ended ‘comprising claim[s],’*” thereby permitting the presence of the “fragrance” disclosed in Garg et al., as discussed below (Office Action, pp. 3, 7, and 10). Applicant has amended the pending Claims to remove any possible open-ended limitations, and added a limitation to require the presence of a sufficient amount of solvent to form the claimed invention. Accordingly, Applicant respectfully requests that the pending Claims now be examined as close-ended narrow Claims, as listed above.

### **1. The invention of Claims 1-10 neutralize odor caused by vaginitis -- without the use of any fragrances.**

As previously explained, a key aspect of the present invention is its ability to neutralize and control odor caused by vaginitis, *without* the use of a fragrance. **Exhibit C** to Applicant’s Response to the Non-Final Office Action, filed on March 26, 2008 under 37 C.F.R. § 132, demonstrated the significant and unexpected ability of the claimed devices and methods to control odor *without* the use of a fragrance. In view of the further amendments to Claims 1-10 and, more particularly, the use of the “consisting of” transitional phrase, the Claims unequivocally *exclude* the use of any fragrance. MPEP § 2111.03 (“the transitional phrase ‘consisting of’ excludes any element, step, or ingredient not specified in the claim.”).

The primary reference that the Examiner relies upon in rejecting the currently-pending Claims is the article “Compendium of Pharmaceutical Excipients for Vaginal

Formulations” by Garg et al. (referred to herein as “Garg et al.”). Garg et al. disclose a host of different vaginal formulations, which are described to be useful for a wide range of different applications, namely, spermicidal contraceptives, cervicitis, vulvovaginitis, vaginal irritation, vaginal acidity maintenance, microbicides, anti-trichomoniasis, cervical ripening, bacterial vaginosis, yeast infection treatments, anti-viral treatments, progesterone supplements, and the list goes on. (Garg et al., p.16-17). The Examiner cites the following composition from Garg et al. on page 3 of the Office Action:

Monesalgi	Tosyl	Starch/Kid	L-lysine acid, water, sodium lactate, potassium sorbate, O-8,	Cleanse external
		Biochem	EDTA, citric acid, dimethyl chloide, fragrance	vaginal area

(Garg et al. p.17). Garg et al. teach that the above formulation is designed to “cleanse [the] external vaginal area,” and clearly employs the use of a “fragrance.”

As the Examiner should appreciate (but did not address in the current Office Action), it is well-settled law that when a claim excludes an element (*e.g.*, a fragrance) that a reference (*e.g.*, Garg et al.) requires, that is the epitome of unobviousness. *See, e.g., In re Freed*, 165 USPQ 570, 572 (CCPA 1970); *In re Duva*, 156 USPQ 90, 94 (CCPA 1967); *In re Fischer*, 179 USPQ 304, 305 (CCPA 1973); *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983); *Ex parte Cordova*, 10 USPQ2d 1949, 1951 (BPAI 1988); *Ex parte Grasselli*, 231 USPQ 393, 394 (Bd. App. 1983); and *Ex parte Kaiser*, 189 USPQ 816 (Bd. App. 1975).

Moreover, it is important to note that the “fragrance” component of the cited Garg et al. formulation is not a ubiquitous component that is recited in the various formulations of Garg et al. That is, it is not a superfluous ingredient that is haphazardly referenced in all formulations. Indeed, among the more than 50 different formulations listed on pages 16-17 of Garg et al., only three (3) formulations recite the use of a fragrance (one of these

three formulations being the formulation that the Examiner cites). Accordingly, the express teaching of Garg et al. is that the formulation cited by the Examiner requires the use of a “fragrance.”

The Examiner further states:

“[e]limination of an element and its function is obvious if the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). Odor controlling agent and fragrance are both added to personal care products to eliminate odors, and it is personal choice to select either or both in the product according to intended use.” (Office Action, p.10).

As an initial matter, the cases cited by the Examiner are completely inapposite. For example, in *In re Larson*, the primary basis for the CCPA affirming the rejection of the claims referenced by the Examiner was that excluding certain “added features [disclosed in the prior art] for increasing cargo capacity such as containers for housing various articles in addition to liquid cargo ...” was an obvious modification. The CCPA agreed with the Board’s reasoning “[t]hat if [the claimed] hollow axle without more has the potential for use as a liquid transfer in appellants’ vehicle, ‘it likewise must have that same potential in the Le Clair et al. vehicle since we find no claimed difference in structure over the reference.’” *In re Larson*, 340 F.2d at 968. In other words, the CCPA seemed to reason that because the prior art – even without the omitted “containers for housing various articles in addition to liquid cargo ...” – could function in the same capacity as the claimed invention, the omission of such containers was obvious. This type of reasoning does not apply here, insofar as only three (3) formulations disclosed in Garg et al. (among the more than fifty (50) different formulations listed on pages 16-17 thereof) recite the use of a fragrance, suggesting that such fragrance is necessary to

control odors using Garg et al.'s formulation, which is not the case with the claimed device (Claims 1-4) and the methods of controlling odor (Claims 5-10).

Similarly, in *In re Kuhle*, in response to the patent applicant's arguments in favor of patentability, the CCPA noted and agreed with the Board's decision that "[d]eletion of elements, such as the switch of Smith and Sherrard, *thereby deleting their function*, was a matter of simplification and obvious expedient." *In re Kuhle*, 526 F.2d at 554-55 (emphasis added). Again, the difference here is that Applicant is not deleting a component (fragrance), and thereby deleting its function (odor control). The Applicant is deleting a necessary component (fragrance) disclosed in the prior art (Garg et al.), while *retaining* its function. The cases referenced in the Office Action do not apply here.

The Examiner echoes the reasoning of these cases, and states that "[e]limination of an element and its function is obvious if the element is not desired ..." (Office Action, p.10). However, this is not a case where "the element is not desired," i.e., a means for controlling odor. Indeed, an important aspect of the invention is to control odor (as recited in Claims 1 and 5). The significant difference between the prior art and the pending Claims is that the device and method of the present invention are capable of controlling odor, *without* the use of a fragrance. This is not a case where the invention is being modified from a prior art reference to exclude a component and its associated function. The invention is excluding a component (fragrance); and *retaining* the function provided by the excluded component, i.e., odor control. When a claim excludes an element (e.g., a fragrance) that a reference (e.g., Garg et al.) requires, that is the epitome of unobviousness. See, e.g., *In re Freed*, 165 USPQ at 572; *In re Duva*, 156 USPQ at 94; *In re Fischer*, 179 USPQ at 305; *In re Marosi*, 218 USPQ at 292; *Ex parte Cordova*, 10

USPQ2d at 1951; *Ex parte Grasselli*, 231 USPQ at 394; and *Ex parte Kaiser*, 189 USPQ at 816.

In view of the foregoing, Applicant respectfully requests that the rejections of Claims 1-10 under 35 U.S.C. § 103(a) be withdrawn.

2. **The “picture claims” – Claims 4 and 7 – have been amended to not only exclude the use of a fragrance, but also to be limited to the specific elements and quantities recited therein.**

Applicant would be remiss not to mention again that Claims 4 and 7 (which represent very narrow “picture claims” of the present invention) recite specific elements, and quantities thereof, which are not disclosed in the collection of prior art cited in the current Office Action. For example, the following limitations are not found in the prior art:

- As discussed above, the portion of Garg et al. that is referenced in the current Office Action requires the presence of “fragrance,” whereas Claims 4 and 7 exclude any use of a “fragrance.”
- The cited prior art does not teach the amount of the odor absorbing agent required in Claims 4 and 7.
- The cited prior art does not teach the amount of antiseptic (cetylpyridinium) required in Claims 4 and 7.
- The portion of Garg et al. that is referenced in the current Office Action requires the presence of “sodium lactate,” whereas Claims 4 and 7 exclude the use of such chemical in the devices and methods claimed therein.

Therefore, in view of the foregoing differences between Claims 4 and 7 and the cited prior art, and further in view of the reasons set forth in Section B.1 above, Claims 4 and 7 should be allowed to issue.

**C. Conclusion**

In view of the Amendments to the Claims and the Remarks above, Applicant respectfully requests that the current rejections under §§ 112 and 103 be withdrawn, and that Claims 1-10 be allowed to issue.

Respectfully submitted,

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